

Table I: Clinical characteristics of patients with hairy cell leukemia at time of starting

BL22

Pt#	Age	Sex	Yrs	Prior Treatment	Circulating	Sites other
			from		HCL cells	than blood/
			dx		X 10 ⁹ /L	marrow
#2	71	F	37	*SPLN,IFN,CdAx4,DCFx2,CdAx1,Rituximab	88	None
#4	54	M	18	*SPLN,IFN,DCFx1,CdAx2,_B4bR,CdAx4	0.690	Abdominal Mass
#9	42	F	3	**CdAx3	0.011	Spleen
#14	46	M	9	@IFN,CdAx2,DCFx2,FAMP,FAMP+CHL, **CHL,Rituximab,DCFx1,IFN	132	Spleen
#15	54	M	25	#SPLN,CdAx1,IFN	0.180	None
#17	61	M	9	**CdAx2,IFN	1.33	Spleen
#18	70	M	2	@CdAx2,IFN,CdAx1	32	Spleen
#20	50	M	2	@CdAx1	0.046	Spleen
#23	45	F	11	@CdAx2,IFN,DCFx1	0.022	Spleen
#25	59	M	25	*CHL+PDN,SPLN,CHL,IFN,CdAx1,DCFx1,CdAx1	4.7	None

#26	56	M	2	@CdAx1,SPLN	44	Abdominal Mass
#27	43	M	5	@CdAx2,PDN,IFN	0.009	Spleen
#28	57	F	5	@CdAx1,IFN,SPLN	0.038	None
#29	37	M	05	@CdAx1,Rituximab	0.026	Spleen
#30	54	M	6	*CdAx2	0.065	Spleen
#31	55	M	21	*SPLN,CdAx3	0.006	None

*No response (NR) to last course of CdA, ** complete remission to last course CdA lasted < 6 mo., @Never in complete remission, #complete remission never documented.

Previous treatment, listed in chronological order, included splenectomy (SPLN), interferon (IFN), cladribine (CdA), deoxycoformycin (DCF), Rituximab, anti-B4-blocked ricin (_B4bR), fludarabine (FAMP), chlorambucil (CHL) and prednisone (PDN). The number of courses of purine analog deoxycoformycin or CdA are listed.

Table II: Dose levels and immunogenicity of BL22 in hairy cell leukemia patients

PT#	DOSE	Antibody
	($\mu\text{g/Kg} \times 3$)	Response
2	3	-
4	6,6,6,10	+ after Cycle 4
9	10,10,20,20	-
14	30x9,40,50,40	-
15	30,30	++ after Cycle 1
17	30,30,30	-
18	30x5, 40x4	-
20	30,30	-
23	40,40	++ after Cycle 2
25	40,40,50,40,40	-
26	50,50,40	-
27	50,50,40,40	-
28	50,50	-

29 40x10 -

30 40x9 -

31 40,40 -

Under dose, each number represents a separate cycle, indicating $\mu\text{g}/\text{Kg}$ intravenous of each of the 3 doses/ cycle. Cycle 2 for patients #15 and 18 was limited to 1 and 2 doses, respectively. High (++) and low (+) neutralizing antibody activity indicates >75 percent and 25-75 percent neutralization of 1 $\mu\text{g}/\text{ml}$ of BL22 in serum, respectively. Patients 14, 18 and 27 received 1, 4, and 2 cycles, respectively, after relapsing.

Table III: Response to BL22 in hairy cell leukemia

PT#	Standard Criteria			Minimal Residual Disease		
	Response	Cycles	Response	BMBx	Blood	Blood
		before CR	Duration (mo)	Immuno	FACS	PCR
2	PD	N/A	N/A	ND	+	ND
4	MR	N/A	4	ND	+	ND
9	CR	2	19+	-	-	-
14	CR	9	8	-	-	-
15	MR	N/A	4	ND	+	ND
17	CR	1	17+	-	-	-
18	CR	4	12, 1+	-	+	-
20	CR	1	13+	-	-	-
23	CR	1	11+	-	-	-
25	CR	3	9+	-	-	-
26	CR	1	10+	-	-	-
27	CR	1	8	+	-	-
28	CR	2	7+	-	-	-

29	PR	N/A	7+	+	-	-
30	PR	N/A	7+	+	-	-
31	CR	1	7+	-	-	-

N/A, not applicable. ND, not determined. Responses were complete (CR), partial (PR), or marginal

(MR), or progressive disease (PD). Patient #18 achieved a second CR.